

How to Make New Drugs More Affordable

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by Devon Herrick

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Over the past several years, a few high-priced drugs have elevated drug spending to a political issue. Patients are more sensitive to rising costs due to increasing deductibles and, because consumers pay more of their drug costs, pharmaceutical companies are less able to pass on high prices without anyone noticing.



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A significant driver of high drug prices is the excessive regulatory regime at the U.S. Food and Drug Administration (FDA). FDA regulatory overreach is exacerbated by a lack of guidance from Congress. To boost competition and hold the line on drug prices, a more rational path to drug approval is badly needed.

The Drug Approval Process

A drug that makes it through the FDA approval process is guaranteed years of high monopoly prices due to regulatory barriers to competition. Increasing competition among innovative drugs could prevent some of the egregious price hikes of the past.

Me-Too Drugs. “Me-too drugs” are new drugs similar to existing ones that treat the same condition. A little over a decade ago, many in the public health community began asserting that follow-on or “me-too” drugs offer little added benefit and are a waste of resources that would be better spent to research novel drug therapies.¹ The FDA seemingly took this criticism to heart; in recent years it has fast-tracked approval of new, first-in-class drugs thought to show promise.

Yet, as with any new drug, a “me-to drug” could take up to 15 years to research, develop and obtain FDA approval. A drug that comes to market one year after a first-in-class drug could have been first-in-class if that research and development team had been just a little faster. Thus, when the FDA discourages me-too drugs it is discriminating against every competitor that did not cross the finish line first. As a result, approvals for expensive drugs to treat rare diseases are at a historic high while approvals of me-too drugs are down. This limits competition within drug classes, leading to higher prices, and limits patient choices — something the FDA is just beginning to acknowledge.²

This restrictive FDA policy is beyond the scope of the “safe and effective” legal standard for new drugs the FDA is required to follow. After drugs are approved, they are often found useful for other conditions. The FDA short-circuits this process of discovery

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by substituting its judgment for that of physicians — in effect, regulating the practice of medicine by limiting doctors' discretion.

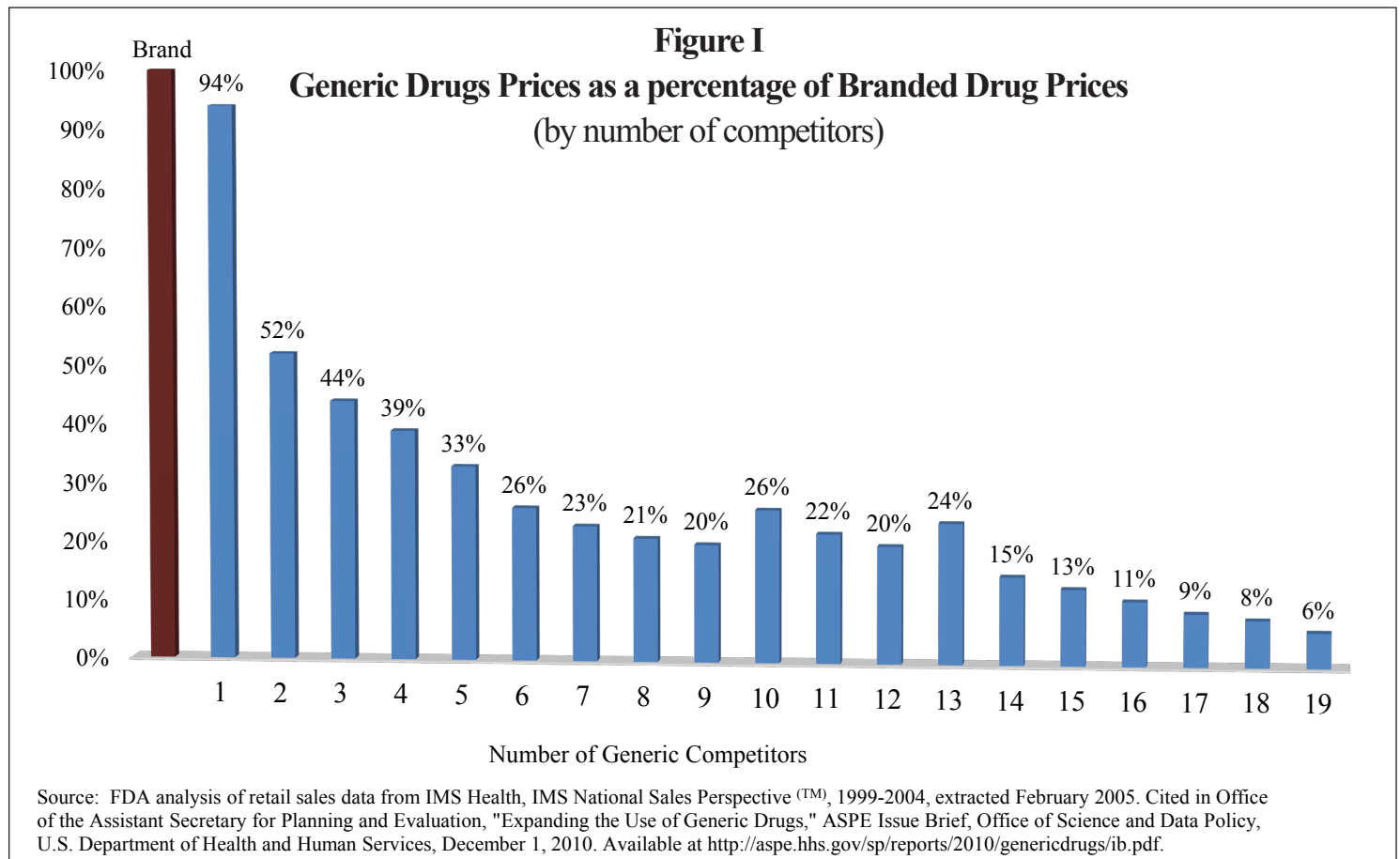
Effects of Drug Competition. Once a new first-in-class drug is approved, similar drugs begin to appear from other drug makers within 2 to 3 years.³ Approving new competing drugs helps hold drug prices in check.⁴ For example, when the hepatitis drug Sovoldi was first approved, its list price was \$1,000 per pill. After a competing product was introduced, the price was soon discounted by more than one-third for large purchasers.

Most of the drugs Americans take (accounting for about 88 percent of prescriptions) are generics.⁵ Generics are inexpensive, comprising only about 28 percent of drug spending. In contrast, patent-protected brand-name drugs constitute 11 percent of prescriptions filled but account for 39 percent of drug expenditures. The remaining 1 percent of drug therapies are specialty drugs, which account for more than one-third of drug spending.⁶

Generally, when brand-name drugs face generic competition, the price falls precipitously.⁷ Research shows that when a branded drug faces competition from only one generic, the price of the competing generic is 94 percent of the price of the brand-name drug [see the figure], on average. However:

- By the time there are two competing generics in a drug class, the average generic price has fallen in half.
- By the time there are five competitors, the price is one-third.
- Moving from six to nine competing generics drops the price by three-fourths compared to the branded drug.

Generic drugs are generally inexpensive because they are no longer protected by patents. It is common for several manufacturers to produce a given generic and compete on price. In contrast, drugs with unexpired patents are sometimes costly. Pharmaceutical companies are free to establish whatever price levels they believe the market will bear and firms that manufacture brand-name drugs



wield significant pricing power.⁸ In some drug classes, there are only one or two patented drugs competing for patients.

Eliminating the FDA bias against bringing me-too drugs to market could slow price increases long before drugs face generic competition. Furthermore, increased access to advanced drug therapies is beneficial to patients because not all patients respond to a given drug in the same way.

Safe and Effective Benchmarks. Another problem that impedes drug development is that different divisions within the FDA use different standards for *safe and effective*.⁹ Whereas one division might merely look for a net benefit (benefits greater than risks), another division may require almost no risk and huge benefits. One division may tolerate little risk, while another might allow significant uncertainty if the drug is the first in its class.

The 21st Century Cures Act, signed into law by President Obama in December 2016, aims to streamline the approval process for new drugs. Rather than exclusively requiring costly double-blind clinical trials, pharmaceutical companies are now able to track patient experiences and test drugs' effects based on other evidence. The Act strengthens an earlier 2012 law allowing the FDA to fast track drugs for "serious or life threatening" conditions, antibiotics and breakthrough therapies.¹⁰ However, this process is not available for follow-on drugs that are similar to existing drugs and the primary benefit of which may be merely holding older drugs' prices in check.

The Drug Supply Chain¹¹

The high price of some drugs became a political issue in 2016. In response to increased public scrutiny, some drug companies began looking for a scapegoat and blamed "the middleman." This is a straw man. What drug makers call the middleman is the industry's supply chain.

The drug supply chain starts with the makers of raw ingredients and includes drug makers themselves, drug wholesalers, pharmacies and drug benefit plans sponsored by employers and insurers. Common sense suggests that the purveyors of raw ingredients, drug makers, wholesalers and pharmacies all want to maximize their revenue by charging prices as high as their customers

will pay. However, in a competitive market with numerous firms competing to sell drugs (and raw ingredients), high prices entice other firms to enter the market. Unfortunately, there are circumstances that inhibit competition from holding prices in check.

Raw Materials Suppliers. Even if multiple manufacturers produce a certain drug, there may be only one or two suppliers of the necessary raw materials.¹² About 40 percent of ready-to-dispense drugs in the United States are imported, but about 80 percent of the chemical precursors used to manufacture drugs sold in the United States come from foreign sources.¹³ The raw material supply chain often runs through developing nations, where political crises, wars, disease outbreaks or weather can affect production of pharmaceutical ingredients or restrict trade.¹⁴

Drug Wholesalers. The wholesale drug industry has undergone tremendous market consolidation in the past few decades. Today, three large firms control nearly 90 percent of wholesale drug distribution.¹⁵ The lack of competitors arguably allows distributors to extract greater profits at the expense of consumers. Market consolidation tends to reduce price competition and make informal collusion among competitors easier to maintain. As a result, pharmacies — especially those lacking significant bargaining power due to their small retail market share — likely pay higher wholesale prices than they would if numerous wholesalers vigorously competed for their business.

Retail Pharmacies. Drugstores stand to both benefit and suffer when manufacturers raise prices. In the short term, profits could be squeezed, but long-term profit margins are likely to rise due to higher prices per prescription.¹⁶ Consolidation in the drugstore industry is reducing the number of competitors, which could lead to higher prices. Measured by revenue, the top five drugstore chains now control more than half of the retail drug market.¹⁷

Pharmacies also attempt to pass on higher drug costs to drug plan members because individuals with drug benefits directly pay for only a small portion of their costs.

Pharmacy Benefit Managers. To keep drugs affordable, health plans often contract with

pharmacy benefit managers. PBMs are large firms that specialize in designing and managing drug benefits for employers, insurers, Medicare Part D and some state Medicaid programs. PBMs use a variety of techniques to control costs. With multiple clients, large national PBMs negotiate lower prices from manufacturers, and therefore possess far more bargaining power than individual firms. PBMs consult with health plan sponsors to determine which drug therapies to include in their formularies, and to encourage enrollees to use cost-effective alternatives. PBMs also check for drug interactions and inappropriate or duplicate prescriptions. Finally, PBMs assemble pharmacy networks, contract with mail-order pharmacies and process pharmacy reimbursements for their clients.

Most Americans belong to a drug plan that manages benefits on their behalf. As a result, for most consumers drugs are very affordable. For those taking more costly drugs, boosting competition would help.

Conclusion

A way to rein-in high drug prices is to inject more competition. Newer drugs would face numerous competitors if it didn't require years and cost \$1 billion or more to bring a new product to market. With more competition, high prices — such as prescriptions that cost \$1,000 per pill or \$2,000 per month — would be impossible for drug makers to maintain. Competition works great in that regard.

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Notes

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